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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,588	12/20/2001	Frederic Andre	SANSYL002	1696

7590 08/11/2004

Patent Department  
Sanofi-Synthelabo Inc.  
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/019,588

**Applicant(s)**

ANDRE ET AL.

**Examiner**

Blessing M. Fubara

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-9 and 11-34 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6-9, 11-23 and 25-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1615

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, amendment and remarks, all filed 04/26/04. Claims 1, 3, 4, 6-9 and 11-34 are pending and of these claims 24 and 34 are withdrawn from consideration (see previous office action). Examiner further acknowledges receipt of the attachment that provides a description of the various EUDRAGIT polymers. It is further suggested that the response to this action indicate claims 24 and 34 as withdrawn if applicants do not wish to cancel those claims but intend those claims to remain as pending

#### ***Claim Rejections - 35 USC § 112***

1. Claim 17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants argue that the “other” does not make the claim indefinite because claim 17 depends on claim 16 and the “other” refers to the immediate or sustained release entity referred to in claim 16.

2. Applicants' arguments filed 04/26/04 have been fully considered but they are not persuasive.

The examiner has reconsidered the rejection and upon further consideration the objection to the term is maintained because it is not clear what “other gellenic entity” contains the active substance. It is respectfully suggested that applicants recite what the other gellenic entity is in place of the “other gellenic entity.” If as applicants contend, the “other gellenic entity” refers to immediate or sustained release entity, then it is suggested that the ‘other gellenic entity be replace

Art Unit: 1615

with sustained or immediate release entity. This raises the issue of what the immediate release entity is, is it tablet, capsule, suspension, powder dosage form or just immediate or sustained release formulation?

Clarification is requested.

***Claim Rejections - 35 USC § 102***

3. The rejection of claims 1, 3, 7, 9 and 11-15 under 35 U.S.C. 102(b) as being anticipated by Heinicke et al (US 5,834,024) is withdrawn because the amendment to claim 1 that now includes cationic or zwitterionic surfactant in the delayed release coated core overcomes the Heinicke reference because Heinicke teaches surfactants in general without disclosing the types of surfactant that would be applicable in the invention.

***Claim Rejections - 35 USC § 103***

4. The rejection of claims 1-4, 6-9, 11-23 and 25-33 under 35 U.S.C. 103(a) as being unpatentable over Andrieu et al. (US 5,589,190) in view of Wilson et al. (6,403,597) because the coating material in Andrieu does not have ammonium group and thus applicants' argument with respect to ammonio methacrylate is persuasive.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 3, 4, 6-9, 11-23 and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0077297) in view of Lerner et al. (US 5,840,332).

Chen discloses tablets, pellet or beads of active agents and also discloses that the active particles may be contained within a capsule (paragraph [0012]). Diclofenac, indomethacin are

Art Unit: 1615

few of examples of the drugs that can be formulated according to the disclosure of Chen (paragraph [0059] and extended list of the drugs are found in paragraphs [0052]-[0106]). The pharmaceutical composition of Chen specifically contains ammonio methacrylate copolymers (paragraph [303]) and zwitterionic surfactants (paragraph [125] and [0127]). The ammonio methacrylate copolymers are the EUDRAGIT type polymers of the E, L, S, RL, RS and NE series (paragraph [303]).

Lerner discloses tablet or pellet or capsule drug delivery composition that comprises diclofenac, indomethacin and dexamethasone (to name a few from the list) (column 6, lines 9 and 10; column 12, lines 43 and 44) contained within a core that also includes combinations of pectin, hydroxypropyl cellulose, lactose, starch, alginic acid, guar gum and carrageenan (column 8, line 35 to column 9 line 20); claim 3 teaches that the ammonio methacrylate copolymers can be of the A or B types.

Regarding the amount of the zwitterionic surfactant relative to the copolymer coating, it is within the purview of the person of ordinary skill in the art to determine the amount effective that would aid in the desired release pattern of the dosage form.

Although Chen discloses that the core particles are coated with EUDRAGIT polymers, the Chen teaching is broad and does not specifically disclose that the ammonio methacrylate copolymers are of the A or B types. However, Lerner discloses that similar drugs such as diclofenac and indomethacin particles can be coated with the A or B type EUDRAGIT. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the active drug particles with the EUDRAGIT copolymers according to Chen. One having ordinary skill in the art would have been motivated to coat particles of diclofenac

Art Unit: 1615

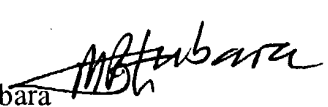
with A or B type ammonio methacrylate copolymers with the expectation of producing a dosage form with the desired delayed/sustained release of the drugs.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification and in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Blessing Fubara  
Patent Examiner  
Tech. Center 1600